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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,670	07/13/2001	Phillip D. Purdy	UTSD:798US	4825
32425 7590 08/27/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT	PAPER NUMBER
			3767	
			MAIL DATE	DELIVERY MODE
			08/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/905,670

Applicant(s)

PURDY, PHILLIP D.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 14-16 and 29-63 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64-69 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 13, 21, 22, 24, 27, 28 and 77 is/are rejected.
- 7) ☒ Claim(s) 4-6, 12, 17-20, 23, 25 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 9,10,14-16, and 29-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9 June 2005. Claims 9,10,14-16 will be rejoined upon allowance; claims 29-63 will not be rejoined.

### *Claim Rejections - 35 USC § 102*

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1,7,11,13,21,24,27,28 are rejected under 35 U.S.C. 102(e) as being anticipated by Harper et al (US 6,436,091)

Harper teaches a method of navigating the subarachnoid space (920,Figs 15-17) comprising: percutaneously introducing a sufficiently flexible guidewire (656) into the spinal subarachnoid space at an entry location; introducing a device over the guidewire (cannula 650), the device having a first passageway to slidably receive, and work with, at least the guidewire, and the guidewire being positioned in the passageway (Fig 9b); and advancing the device over the guidewire and within the spinal subarachnoid space at least more than 10 centimeters from the entry location (see tables Col 14). Regarding claim 7, the device (650) includes a second passageway (652).

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Regarding claim 13, medication (via 652) is delivered to an intracranial subarachnoid space.

Regarding claim 24, the position of the device is monitored via radio-opaque material (Col 5 1<sup>st</sup> full paragraph).

Regarding claim 27, material (infusate) is introduced and can be placed near a cranial nerve in order to treat a neurological condition.

Regarding claim 28, the material can be genetic.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper in view of MICHAELI (US 6,328,694).

Harper teaches a method of inserting a device into the subarachnoid space and delivering a medication thereto. Harper does not teach removing a portion of the brain. However, in the placement of the dilator, catheter, and capsule, it would seem that a portion of the brain tissue would be removed. In light of Harper's silence on this point, Harper is referenced. Harper discusses a method of performing brain surgery wherein a portion of the brain is removed (Col 2, lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of

Harper to include the explicit teachings of removing brain tissue as taught by Harper in order to increase the chance of recovery for the rest of the brain and improve effectiveness of treatment.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harper. Harper does not explicitly teach the flushing of cerebrospinal fluid to remove blood, but does teach that a sample of fluid can be removed through the guidance needle and tested for the presence of CSF. It would have been obvious to one of ordinary skill in the art at the time the invention was made to remove any blood present in the removed CSF in order to collect a more pure sample for testing.

5. Claim 8,24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harper in view of PUTZ (US 6,004,262).

Harper discloses a cannula inserted into the subarachnoid space and a guidewire inserted into the space. Harper does not teach the use of an endoscope inserted into the dilator or cannula. Putz discloses the use of an endoscope to assist in navigation through the subarachnoid space (Col 3 line 33- Col 5 line 30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert an endoscope into the channel of the infusate of Harper in order to improve visualization of the surgical site and avoid errors in surgery.

6. Claims 25,26, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper in view of HOFMANN (US 6,330,466

Harper discloses a cannula inserted into the subarachnoid space and a dilator inserted into the space. Harper does not teach the use of an electrode being placed near brain

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tissue. Harper's device is perfectly capable of inserting an electrode near brain tissue. Hofmann teaches that it is well known in the art to place electrodes near the brain for the purpose of stimulating or recording. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the insertion procedure of Harper in order to insert the electrode of Hofmann near the brain tissue in order to provide treatment to a patient.

***Allowable Subject Matter***

7. Claims 64-69 are allowed.
8. Claims 4-6, 12, 17-21, 23, 25, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

9. Applicant's arguments filed 19 June 2007 have been considered but are moot in view of the new grounds of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizab*  
*Walters*  
*7/11/07*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*